

Applicant : Lars Tommy Westbye, et al.  
Appl. No. : 10/626,218  
Examiner : Catherine Witczak  
Docket No. : 706737.4003

### **Remarks/Arguments**

Reconsideration of this application is requested. Independent Claims 1, 25, 33, and 34 have been amended to more completely and accurately define the subject matter being claimed. Claim 17 has been amended to correct the claim of dependency.

#### I. Section 102 Rejection

Claims 1-13, 15 and 17-48 stand rejected under 35 USC §102(e), as being anticipated by Fathallah et al (USP 6,805,686). “[A] claim is anticipated if each and every limitation is found either expressly or inherently in a single prior art reference.” Celeritas Techs., Ltd. v. Rockwell Int’l. Corp., 150 F.3d 1354, 1361, 47 U.S.P.Q.2d 1516, 1522 (Fed. Cir. 1998). The standard for lack of novelty, that is, for “anticipation,” is one of strict identity. Trintec Indus., Inc. v. Top-U.S.A. Corp., 295 F.3d 1292, 1296, 63 U.S.P.Q.2d 1597, 1600 (Fed. Cir. 2002). In the present Office Action, the Examiner’s rejection is based on the Fathallah reference, which fails to show all of the elements of the claimed invention.

The Fathallah reference is directed to an autoinjector that includes a cover or shroud that extends to cover the needle following injection of the dose. See, e.g. Figs. 2a-e, 4a-d. However, the syringe 100 of the Fathallah reference is not designed to receive a needle guard such as that claimed by Applicant. Instead, as shown in Figures 4a-d, the shroud or needle cover of the Fathallah system is coupled with the autoinjector system. If a user of the Fathallah system attempts to remove the reservoir, plunger and needle assembly from the autoinjector system, the shroud does not provide any protection from needle sticks. The shroud 700 only protects the user when the needle is secured within the autoinjector system. Thus, a user of the Fathallah system is potentially exposed to needle sticks during removal of the needle from the autoinjector system because the shroud is a separate portion of the system.

In contrast, the medical injection system and methods claimed by applicant comprise a needle guard system which is housed within an autoinjector system. Upon completion of the injection of the dose, the needle guard can be removed from the autoinjector system with the shield of the needle guard extending over the needle. Therefore, users of Applicant’s system can

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safely reload the autoinjector system with another pre-filled medical cartridge and not be exposed to potential needle sticks. Applicant's system, as claimed, is therefore patentably distinguishable from the Fathallah system for at least this reason.

II. Section 103 Rejections

Claim 16 is rejected under 35 USC § 103 as being unpatentable over Fathallah in view of Holman (USP 5,104,380). As demonstrated above, Fathallah fails to disclose, teach or suggest each and every element of independent claim 1 from which claims 16 depends, and therefore, it is respectfully submitted that claim 16 is not obvious in light of the combination of Fathallah and Holman.

III. Conclusion

In view of the foregoing, favorable reconsideration of this application and a Notice of Allowance is earnestly solicited. Should the Examiner have any questions or comments, the undersigned can be reached at (949) 567-6700. The Commissioner is authorized to charge any fee which may be required in connection with this Amendment to deposit account No. 150665.

Respectfully submitted,  
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